

PLEASE READ ENTIRE CONTENTS BEFORE USING INSTRUMENT

PRECAUTIONS

ELECTRONIC IMPLANTS & SENSORS

DO NOT use any device which has separated segments or cuts or openings in the probe body caused by damage or wear and tear.

DO NOT ultrasonically clean, autoclave, or use ionizing radiation. Follow appropriate cleaning and sterilization procedures as stated in our Cleaning and Sterilization section enclosed.

DO NOT use silicone fluid or grease, as these materials may swell and weaken the tubing which comprises the probe's outer sheath.

DO NOT allow the sensors to impact hard surfaces. This may permanently damage the sensors.

TAKE CARE to handle the devices and silicone tubing in such a way as to avoid even minor nicks and cuts.

DO NOT use Electrocautery Equipment during implantation or closing, as it may damage strain gages, sensors and electronics. Electrocautery procedures should be completed prior to implantation of the device or sensors.

TO AVOID INDUCING EXCESSIVE CALIBRATION SHIFT

Precalibration should be performed in water at a temperature as close to 37° C as possible.

DO NOT apply pressures greater than ± 600 mmHg. When determining whether sensors are operating, observe the output signal while applying pressure. **DO NOT** apply pressure with a fingernail or sharp object, which may create high localized stresses.

CLEANING AND STERILIZATION

Konigsberg Instruments **DOES NOT perform sterilization** of devices prior to shipment. Proper sterilization of a device is the responsibility of the clinician conducting the procedure. The following recommendations are intended to aid in the cleaning or sterilization of a Konigsberg device without causing damage.

CLEANING: Proper cleaning of the device will be achieved by following the disinfectant manufacture's detailed instructions and/or your hospital's disinfection protocol for the disinfectant solution your organization specifies.

Prior to disinfecting any portion of the device it should be gently washed in hot water and non-oily or mild soap solution such as Ivory Flakes.

DO NOT use synthetic detergents or petroleum-based soaps on silicone tubing as these may be absorbed by the silicone and subsequently leached out in prolonged use. For critical or prolonged usage, rinse copiously in hot running water (less than 50° C); follow with a thorough rinse in fresh, pyrogen-free distilled water.

STERILIZATION

DO NOT ultrasonically clean, autoclave, or use ionizing radiation to clean or sterilize devices.

The following information is supplied as a guide for cleaning and sterilizing Konigsberg Instruments' implantable devices. We cannot guarantee any specific methods and all disinfectants should be used following their manufacturers' recommendations for proper dilution, sterilization time, and rinsing. Konigsberg Instruments, Inc. assumes no liability for damage due to improper forms of cleaning and sterilization of the device.

Gas Sterilization

The ETO Sterilization method is recommended. BUT the time required for complete outgassing of residual ETO and other ETO by-products from the silicone tubing and coatings should be verified by the machine manufacturer. Avoid ETO Sterilization at high pressure (pressure must not exceed ± 600 mmHg); the devices **MUST NOT** be exposed to temperatures above 55° C. Outgassing must be at ambient pressure over several days.

Liquid Sterilization (Compensation Module must not be immersed in any liquid solution)

CIDEX OPA or CIDEX 14 and CIDEX 28 day solutions manufactured by Johnson & Johnson are forms of liquid sterilization and are approved for use with Konigsberg Instruments probes. Enzol is fully compatible with any of the Cidex products listed here. For information on Enzol, Cidex OPA, Cidex 14 and Cidex 28 day solutions call Johnson & Johnson in Irvine, California, USA 1-800-255-2500.

KONIGSBERG INSTRUMENTS, Inc. (KII) LIMITED WARRANTY

ALL NEW DEVICES ARE GUARANTEED TO OPERATE WITHIN THEIR SPECIFIED ACCURACY FOR A PERIOD OF ONE YEAR FROM THEIR DATE OF SHIPMENT, UNDER THE CONDITIONS SPECIFIED HEREIN. DEVICE REPAIRS ARE GUARANTEED FOR A PERIOD OF 90 DAYS AFTER DATE OF SHIPMENT.

KII AND/OR SELLER ARE PROVIDING THIS WARRANTY IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE. KII'S SOLE OBLIGATIONS UNDER THIS WARRANTY ARE AS SET FORTH HEREIN. IN NO EVENT SHALL KII BE LIABLE FOR ANY LOST REVENUE OR PROFITS, OR DIRECT, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND.

THIS WARRANTY IS LIMITED TO REPAIR OR REPLACEMENT, AT OUR OPTION, AT NO CHARGE, ON INSTRUMENTS WITH DEFECTS IN MATERIALS OR WORKMANSHIP, WHICH ARE RECEIVED AT OUR FACTORY AT PASADENA, CALIFORNIA, USA WITH ALL RETURN SHIPPING CHARGES PREPAID.

WHILE PRESSURE TRANSDUCERS MAY BE REWIRED MANY TIMES, THEY CANNOT BE REPAIRED INDEFINITELY. EACH TIME A TRANSDUCER UNDERGOES CATEGORY I OR II REPAIR IT BECOMES MORE LIKELY THAT AFTER REPAIR IT MAY NOT MEET ITS ORIGINAL SPECIFICATIONS, OR MAY FAIL DURING OR AFTER THE REPAIR IS COMPLETE. AS A RESULT, WE CANNOT PROVIDE A WARRANTY AFTER THE THIRD CATEGORY I OR II REPAIR. WE WILL REPAIR A TRANSDUCER FOUR OR MORE TIMES IF ASKED, BUT IF A TRANSDUCER FAILS, OR FAILS TO MEET ITS ORIGINAL SPECS AFTER THE THIRD REPAIR NO WARRANTY WILL BE GIVEN AND A CHARGE WILL BE APPLIED TO THE RESULTING REPAIR.

THIS WARRANTY DOES NOT APPLY TO, NOR IS THERE ANY OTHER WARRANTY GIVEN ON INSTRUMENTS NOT INSTALLED, IMPLANTED OR OPERATED IN ACCORDANCE WITH SPECIFICATION, OR WHICH HAVE BEEN SUBJECT TO MISUSE, ACCIDENT, OR WHICH HAVE BEEN DISASSEMBLED BY ANYONE OTHER THAN MANUFACTURER. DETERMINATION OF WHETHER THE DEFECT OR NON-CONFORMING CONDITION IS DUE TO DEFECTS IN MATERIAL OR WORKMANSHIP, OR IS DUE TO MISUSE OR ABUSE SHALL BE SOLELY AT THE DISCRETION OF KONIGSBERG INSTRUMENTS, INC.